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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SPECTOR, LORRAINE	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 01/13/2004

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/944,413	BAKER ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-29 and 32-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-29 and 32-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *16*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Part III: Detailed Office Action

Claims 27-29 and 32-47 are pending and under consideration. Applicants indicate claims 22-26 and 30-31 as being withdrawn. Applicants are advised that "withdrawn" is not synonymous with "cancelled", but rather is used to refer to non-elected claims which have not been cancelled. It would appear that applicants intend cancellation of claims 22-26 and 30-31. Accordingly, the Examiner will not act on those claims, and requests that, in response to this Office Action, applicants file another amendment clearly indicating the cancellation of the claims.

The pending claims are directed to PRO243, SEQ ID NO: 7, which is encoded by SEQ ID NO: 6, DNA 35917-1207, deposited as ATCC 209508.

Priority determination:

According to the priority statement of 8/26/02, it appears that the claimed subject matter defined in the instant application is supported by the parent application serial no. PCT/US99/28301, filed 12/1/99. Based on the information given by applicant and an inspection of the patent applications, the examiner has concluded that the subject matter defined in this application is supported by the disclosure in application serial no. PCT/US99/28301, filed 12/1/99 but is not supported by any of the others because the previous disclosures do not present any enabled utility for the claimed protein. Specifically, PCT/US98/25108 does not identify PRO243 as human chordin, and does not enable the use of PRO243 for induction of fetal hemoglobin synthesis. Accordingly, the subject matter defined in claims 22-34 has an effective filing date of 12/1/99.

Applicants have argued this finding in the response filed 5/21/2003. Applicants argue that new claims 35-47 are supported by PCT/US99/28301 at least at pages 10, 18, and 39. This argument has been fully considered but is not deemed persuasive because the Examiner has examined that application (in the form of the US home copy) at those pages, and finds not specific substantial or credible assertion of utility for nucleic acids encoding PRO243 at those pages. Applicants further argue that PCT/US98/25108 discloses "various therapeutic and diagnostic applications at pages 2-3, 23, 29, and 46, Figures 6A-6B and 7, and Examples 4, 5, and 30. Further, at page 20, Applicants describe the activity of PR0243 being the ability to bind and affect (block or otherwise modulate) an activity of chordin involving the regulation of

notochord and muscle formation." This argument has been fully considered but is not deemed persuasive because at pages 2-3 of the '108 application, the discussion is drawn to chordin itself; PRO243 is merely described as having "homology to chordin", not as *being* chordin. At page 22 of the '108 application (not page 23 as stated by applicants), it is stated that PRO243 is a *member* of the chordin family, and "may possess the ability to influence notochord and muscle formation by the dorsalization of the mesoderm". This is not considered to be a substantial assertion of utility as it is (a) speculative, and remains unsubstantiated, and (b) it is not clear what readily available utility under 35 U.S.C. §101 would be envisioned as resulting from such activity even if it *were* to be substantiated. The remaining "utilities" at pages 37, 47-51 and 73-74 are merely uses to further determine the properties of PRO243, and do not constitute specific or substantial assertions of utility. Applicants further argue that provisional application number 60/067411 discusses the preparation and use of chording in "hybridization probes, chromosome and gene mapping, and generation of anti-sense sequences." This argument has been fully considered but is not deemed persuasive because none of these assertions is specific, as such could be asserted for any nucleic acid isolated from a human (or any other species), and each would constitute mere use for further research to determine the properties of the claimed nucleic acids. No readily available, specific, substantial and credible assertion of utility is found in that provisional application.

In view of the above, the Examiner maintains that the priority date for the currently claimed invention remains at 12/1/99.

Formal Matters:

Applicants have submitted a new form PTO-1449, filed 5/21/03 containing additional identifying information regarding the BLAST results. According to the dates thereon, the BLAST results do not constitute prior art, the given dates being 1/8/2002.

The new title of the invention is acknowledged.

The declaration by inventor Eaton is acknowledged.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 35-47 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 5,846,770 (LaVallie et al).

La Vallie et al. disclose human chordin, see SEQ ID NO: 2. SEQ ID NO: 2 of LaVallie et al. differs from SEQ ID NO: 7 of the instant application only at a single residue, residue 70. Fusion proteins are also disclosed, see abstract for example. With respect to the functional limitation "hemoglobin inducing", as the protein of LaVallie is greater than 99.5% identical to SEQ ID NO: 7, said characteristic is, in the absence of evidence to the contrary, presumed to be inherent to the protein of LaVallie et al. It is unlikely that the single amino acid difference between SEQ ID NO: 7 and the protein of LaVallie et al. affects function. The structural limitations of claims 38-47 are all possessed by LaVallie's protein. In such a case, the burden is on Applicants to show that the protein of LaVallie et al. does not possess the stated function. See *In re Swinehart and Sfiligoj,* 169 USPQ 226, wherein it was stated that "Mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art; ", and further held that where Patent Office has reason to believe that the functional limitation may be inherent, that applicant may be required to prove otherwise.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27-29 and 32-33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over LaVallie et al., U.S. Patent Number 5,846,770. This rejection is maintained for reasons set forth in the previous Office Action.

As discussed above, La Vallie et al. disclose human chordin, see SEQ ID NO: 2. SEQ ID NO: 2 of LaVallie et al. differs from SEQ ID NO: 7 of the instant application only at a single residue, residue 70. The proteins are over 99.5% identical.

The courts have long recognized that sequencing errors can occur (*Ex parte Maizel*; 27 USPQ2d 1662, BPAI 1992, see especially pp. 1663 and 1666). The instant specification also recognizes that the sequences disclosed in their sequence listings and Figures may not be exact. Therefore, it is reasonable to expect that the single amino acid difference at position 70 of SEQ ID NO: 2 of the instant application and LaVallie et al. may be the result of a sequencing error, and that the actual clones of the instant application and LaVallie et al., in fact, have identical sequences.

The examiner is unable to determine whether the prior art disclosures actually possesses the characteristic of the sequence of SEQ ID NO: 2. Under such circumstances, where the product seems to be identical, then the burden shifts to applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. Note the case law of *In re Best* 195 USPQ 430, 433 (CCPA 1977).

Applicants traverse that the difference between LaVallie et al. *could* be real, and *could* result in a difference in function of the protein. This argument has been fully considered but is

not deemed persuasive because applicants have not met the burden set forth by *In re Best* 195 USPQ 430, 433 (CCPA 1977), specifically that where the product seems to be identical, then the burden shifts to applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. Applicants further argue that La Vallie was silent with respect to hemoglobin inducing activity. This argument has been fully considered but is not deemed persuasive because such activity would be inherent to the protein of La Vallie et al. "Mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art; see *In re Swinehart and Sfiligoj* 169 USPQ 226.

Claim 34 remains rejected under 35 U.S.C. 103(a) as being unpatentable over LaVallie et al. as cited above in view of Hopp et al., U.S. Patent Number 5,011,912for reasons of record. Applicants traversal has been fully considered but is not deemed persuasive for reasons cited above.

Advisory Information:

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M. ***Effective 1/21/2004, Dr. Spector's telephone number will be 571-272-0893.***

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623. ***Effective 1/21/2004, Dr. Kunz' telephone number will be 571-272-0887.***

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228. ***Effective 1/21/2004, Dr. Spector's fax number will be 571-273-0893.***

Lorraine Spector

Lorraine Spector, Ph.D.
Primary Examiner

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1/9/2004